BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

PATENT SPECIFICATION

DRAWINGS ATTACHED

847,914

Date of Application and filing Complete Specification March 14, 1958.

No. 39985/59.

[Divided out of No. 847,913].

Complete Specification Published 60.

Index at Acceptance:—Class 81(2), Z3C(1A:4).

International Classification:—A61m.

COMPLETE SPECIFICATION

Sterilizable and Sterilized Hypodermic Syringe Assembly

I, EDGAR HENRY WILBURN, a citizen of the United States of America, of 68 Wilson Avenue, Rutherford, State of New Jersey, United States of America, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The present invention relates to hypodermic syringe devices for injecting parenteral liquid medicaments and, more particularly, to the types intended to be loaded by the operators just prior to injective use although not limited to the latter; and the present application is a division of my pending application No. 8224/58 (Serial No. 847,913).

A general object of the present invention is to provide such devices wherein the parts may be readily manipulated or assembled together in relative positions permitting thorough sterilization of all parts intended to contact parenteral liquids with which they are to be loaded for injective use in the patient's body, and so that internally they or parts thereof will after such sterilization be protectively isolated from airborne bacteria or closed off in a manner for efficient maintenance of such sterilized condition through subsequent handling preceding loading, such as that which may attend storage and distribution to the ultimate users.

A more specific object of the invention is to provide in such syringe assemblies protective closure means associated with a chamber-providing barrel structure which under one condition provides an open sterilizing fluid flow passage leading from the surrounding atmosphere directly to a space within such protective closure means for flow through to and from the latter of sterilizing fluid or gaseous medium, heated if desired, to or from the liquid housing chamber of the barrel structure, and which under another condition effectively blocks flow through such passage of airborne bacteria for maintaining efficiently a sterilized condition while permitting simple preparation for loading and then injective use.

Another object of the present invention is to provide in such assemblies manipulatable rear end opening and closing or valving means of a protective nature to employ with isolating front end means, whereby flow of sterilizing fluid through the entire assemblies and about their internal parts may be readily permitted in an efficient cleansing manner, and which thereafter will allow in a simple manner efficient closing off of the rear end and isolating of the front end from airborne bacteria to retain the sterilized condition of the assemblies and internal parts thereof.

A further object of the present invention is to provide such syringe assemblies in forms whereby injective needle means thereof are subjected to such sterilizing flow of cleansing fluid and then securely isolated in housing structures of the assemblies effectively to maintain their sterile condition until injective use.

Still another object of the invention is to provide such assemblies in a form in which means securely closes off or houses the syringe front end structure which may include injective needle means, and means effectively closes off the rear end of barrel structure with, if desired, piston means housed in the latter, such closed construction and means thereof effectively maintaining until manipulation for hypodermic use sterile condition of the interior of the assembly and parts thereof which may have been attained by heat radiation and/or conduction after the parts were brought together in a manner to form the closed assembly.

A still further object of the invention is to provide such a hypodermic syringe device featuring injective needle means permanently carried by the front end of the barrel struc-

[Price 3s. 6d.]

ture with the latter fitted with parenteral liquid-expelling piston means, the injective needle means being effectively covered by removable cap means efficiently isolating it from airborne bacteria with the piston means providing valving means and protective hood structure together permitting ready and effective internal sterilization and maintenance of internal sterile conditions until loaded for injective use.

Another object of the present invention is to provide in such assemblies manipulative piston means each of which includes a hood structure which provides at the rear end of the barrel structure a valving device which in a retracted position of the piston is in valve open position to permit ready through flow of sterilizing fluid while remaining protectively telescoped with the barrel structure, the forward position of the piston means providing closure of the valve means.

A still further object of the present invention is the provision of a structural embodiment of the device which is readily and economically constructed on a mass production basis and which while permitting efficient sterilization and operation thereof allows discard after a single injective use.

Other objects of the invention will in part be obvious and will in part appear hereinafter.

The invention accordingly comprises the features of construction, combinations of elements, and arrangements of parts, which will be exemplified in the constructions hereinafter set forth, and the scope of the invention will be indicated in the claims.

For a fuller understanding of the nature and objects of the invention, reference should be had to the folowing detailed description taken in connection with the accompanying drawings, in which:—

Fig. 1 is an axial section of an embodiment of the hypodermic syringe of the present invention, illustrating relative initial positions of parts which will permit passage through said syringe of sterilizing gaseous medium;

Fig. 2 is an elevational detail, with parts broken away and in section, of the front end of the barrel and associated rear end of the front end protective cap structure of the Fig. 1 embodiment;

Fig. 3 is a transverse section taken substantially on line 3-3 of Fig. 1;

Fig. 4 is a transverse section taken substantially on line 4-4 of Fig. 1;

Fig. 5 is an end elevational view of the structure shown in Fig. 1 as viewed from the capped front end thereof;

Fig. 6 is an axial section of the embodiment illustrated in Figs. 1 to 5 incl., showing the relative positions of parts after they have been sterilized and then telescoped together to close off passages which were provided for passage of sterilizing gases with the parts in the relative positions shown in Fig. 1;

Fig. 7 is a perspective view to a smaller scale of the structure shown in Fig. 6 and with the parts in the same relative positions;

Fig. 8 is an exploded perspective view, with parts broken away and omitted, of the structure shown in Fig. 7;

Fig. 9 is a side elevational view, illustrating manipulation of parts of the embodiment of the hypodermic syringe structure illustrated in Figs. 1 to 8 incl. to draw into the barrel chamber a charge of parenteral liquid;

Fig. 10 is a side elevational view of the syringe structure shown in Fig. 9 but taken in a plane normal to that in which the Fig. 9 structure is viewed;

Fig. 11 is an axial section taken substantially on line 11-11 of Fig. 10, showing the syringe structure loaded with parenteral liquid and made ready for hypodermic injection of contents;

Fig. 12 is an axial section of the embodiment of the hypodermic syringe structure shown in Fig. 1 to 11 incl., illustrating piston ejection of parenteral liquid contents into a person's vein;

Fig. 13 is a front end elevational view of a piston structure similar to that of the embodiment illustrated in Figs. 1 to 12 incl., illustrating strengthening of flexible arms of the cap means thereof;

Fig. 14 is a side elevational view, with parts broken away and in section, of a modified form of barrel and front end protective cap structure which may be employed to advantage in the hypodermic syringe structure illustrated in Figs. 1 to 12 incl.;

Fig. 15 is a perspective view of finger wing structure embodiment in the syringe assembly illustrated in Fig. 14;

Fig. 16 is an enlarged axial section with parts broken away of barrel front end and associated cap structures of the embodiment of Fig. 14, showing the valved passage for sterilizing gases in open condition;

Fig. 17 is a side elevational view substantially to the scale of Fig. 16, with parts broken away and in section, of the structure shown in Figs. 14 and 16, illustrating closure of the valved passage for the sterilizing gases;

Fig. 18 is a side elevational view, with parts broken away and in section, of a modified form of the barrel front end structure, needle mount and protective cap means, illustrating in full lines the relative positions of parts when the valved passage provided thereby is in open condition and in dot-dash lines the relative positions thereof when the valved passage is closed;

Fig. 19 is a view similar to Fig. 18, illustrating still another form of hypodermic syringe structure of the present invention with the valved passage open and featuring a resilient guide strip which upon withdrawal of the protective cap prevents contamination

by means of the lateral or radial movement of the injective tip of an injection needle included in the assembly;

Fig. 20 is a plan view of the protective resilient guide strip illustrated in Fig. 19 in flat initial form before being doubled back for insertion in the protective cap;

Fig. 21 is a sectional view, with parts broken away, taken substantially on line 21-21 of Fig. 19;

Fig. 22 is a view similar to Fig. 19 illustrating manipulation of the cap to close the valved passage.

Referring to the drawings, in which like numerals identify similar parts throughout, it will be seen that the present invention involves the provision of sterilizable hypodermic syringe assemblies of various types and forms comprising in combination a syringe chamber or a barrel structure which has or is to be provided with means for injecting parenteral liquid medicaments, e.g., cannula means or injective needle devices, means to expel the parenteral liquid contents of the chamber or barrel, and a removable cap means which protectively houses parts thereof and isolates portions protectively from airborne bacteria in the surrounding atmosphere or air to maintain the sterile condition of parts of the syringe assemblies until such time as injective use thereof is desired. In various embodiments protective cover or closure means are provided at both ends of barrel structure to isolate the interior thereof with, if desired, suitable injective needle means housed at the front end and preferably piston means reciprocatively located in the barrel structure, the parts and interiors thereof having been effectively sterilized with the closure or isolating means assuring maintenance of the sterile condition of parts. If sterilization is to be effected without through flow of sterilizing fluid, such as by heat radiation and/or conduction, the sterilizing is accomplished after the construction or assembly is protectively closed; but if sterilization is to be effected by through flow of sterilizing fluid the structure of the isolating cap means is such as to provide open sterilizing fluid flow passages or ways for effective sterilization of parts of the assembly. The passages or ways have associated means preventing or blocking flow therethrough into the interior of the assembly, after the latter has been suitably sterilized, of airborne bacteria or air laden with bacteria. Certain embodiments employ the cap means in a manipulative form movable to passage-open position for permitting flow thereinto or therethrough of sterilizing fluid and which may then be simply manipulated to close the valved passages or ways. In some modifications a valved sterilizing-fluid passage or way is provided at the protective cap means and leads from the atmosphere exterior of the cap and barrel means directly to the space within the cap means so that sterilizing fluid may flow into and out of the latter and about the structure housed by it *via* the liquid outlet passage through the barrel front structure which provides the injective outlet for the parenteral liquid. The terms "passage" and "way" are used herein in the sense of one or more paths of flow since part of a flow passage or way may be provided by a single or plurality of grooves, notches, holes, and the like; and the flow of sterilizing gaseous medium therethrough may be in either direction as conditions may dictate.

In the embodiment illustrated in Figs. 1 to 12 incl., barrel structure 50 may be suitably molded from any suitable material which preferably may be a plastic of a composition substantially non-contaminable by parenteral liquid to be loaded thereinto and injectively discharged therefrom. For example, barrel 50 may be molded from polyethylene which is somewhat elastic when thin. Barrel means 50 preferably comprises a front end structure 51, including a head cross wall 52 carrying an outwardly-projecting boss 53 through which is fixed the rear end 54 of an injective cannula or needle 55 having its tip 56 sharpened for facilitating subcutaneous insertion. The barrel front end structure 51 also includes a forwardly-extending cylindrical flange 57 arranged concentric with the needle-anchoring boss 53 to provide therebetween an annular groove 58. As is illustrated in Figs. 2 and 3, the inner cylindrical wall 59 of the circular flange 57 is provided with a plurality of longitudinally-extending notches 60-60 which extend only partially of the full depth of the groove 58 to retain a circular bottom sealing zone 61 of the cylindrical inner wall 59. The barrel structure 50 preferably has a cylindrical side wall 62 which defines a cylindrical bore 63 closed off at the front end by head structure cross wall 52 and with which the bore of cannula or needle 55 communicates. Thus, the cannula or needle here constitutes the liquid outlet passage for the parenteral liquid chamber defined by the cylindrical side wall 62 and the cross wall 52. Near the rear end of the barrel structure 50 bore 63 preferably is provided with an internal constriction or circular rib 64 to serve as a plunger means or piston plug stop, as is more fully explained hereinafter. Rearwardly of the stop rib 64 the barrel bore 63 is counterbored at 65 to provide thereby a socket preferably having a diameter somewhat larger than the diameter of the bore 63 and for a purpose to be indicated later. Such counterboring 65 provides the rear zone of the barrel cylindrical wall 62 with a substantially thinner walled zone 66 which, by virtue of being thinner, is somewhat more flexible. Within the rear zone 66 of the barrel wall is provided

an outside annular groove 67, preferably located near the rear edge 68 of the barrel which rear edge is in the form of circumambient lateral rear end structure defining an open chamber rear end, and which may have a plurality of functions, as explained hereinafter.

An elongated thimble-like cap means or tubular cap structure 69 is provided for housing and isolating the structure defining the liquid outlet passage, e.g. the needle 55, and having a closed front end 70, a substantially cylindrical side wall 71, and a cylindrical rear end 72 which snugly fits for telescopic sliding action within the cylindrical inner wall 59 of the circular flange 57. The protective cap 69 may be molded from any suitable material, such as plastic, and may be substantially rigid when formed of more brittle plastic material, such as poly-styrene, or if desired may have some elasticity if molded from a more elastic plastic material, such as polyethylene. Frictional fit retains the cylindrical rear end 72 of the cap 69 within annular flange 57 in the position illustrated in Fig. 1. In such position of cap 69 fluid or gaseous medium may flow to or from the exterior of the cap and barrel structure 50 through the passage or way provided successively by longitudinal notches 60-60, the open portion of annular groove 58 behind the back edge 73 of the rear end of the cap, the space between the boss 53 and the inner wall of the cap, the space 74 within the cap, and the bore of the needle 55. This will be considered the valve open position of the cap 69 in which the valved sterilizing-fluid passage or way at the cap rear end is open.

Plunger means 75 of the syringe assembly of Figs. 1 to 12 incl. may include a suitable piston structure 76, preferably in the form of an elongated shaft or stem having an externally-threaded head end 77 threadably received or mounted within an internally-threaded socket 78 in the rear end of a piston plug 79 which may be molded from suitable elastic material, such as rubber or the like. The rear end or root 80 of the piston shaft or stem 76 preferably is made or molded integral with a plugging element 81 which may be frustoconical in shape, as shown, and of such dimensions as to wedge into the open rear end of the barrel counterbore 65 for secure and sealing closure thereof. The plugging element 81 and the piston shaft 76 preferably are housed coaxially within a rear cap 82 which may be molded integral therewith. Preferably the rear cap 82 is elongated and provided with a substantially cylindrical bore 83 to define an elongated skirt or hood, as shown. Skirted cap or hood 82 defines with the conical surface of the plugging element 81 a V-shaped annular groove 84 into which the rear edge 68 of the barrel may be wedged for enhancing the sealing of the rear end of the barrel chamber or bore 63. The plunger means or assembly 75 comprising piston shaft 76, plugging element 81 and rear cap means 82 may be molded integral from any suitable material, such as rigid, semi-rigid, or somewhat elastic plastic, e.g., polystyrene or polyethylene.

The side walls of the front end or skirt of the rear cap 82 preferably are provided with a fluid passage or flow way, such as one or more side openings, which may be in the form of a pair of diametrically-opposed notches 85, 85 extending from the front edge 86 longitudinally back an appreciable distance, as is best seen in Figs. 1 and 7 to 10 incl. Such diametrically-opposed notches 85, 85 define therebetween a pair of diametrically-opposed legs 87, 87, each of which is provided internally near edge 86 with a circular rib segment 88 which snaps into the annular barrel groove 67 in the outward or rearward position of the plunger assembly 75.

In order to facilitate manual grasp and manipulation of the hypodermic syringe device illustrated in Figs. 1 to 12 incl. barrel 50 is provided with suitable finger grasps, such as a pair of diametrically-opposed, laterally-extending finger wings 89, 89 which are receivable in the diametrically-opposed notches 85, 85 of the skirt of the rear cap 82 to permit the latter to be pushed completely forward in order to expel all parenteral liquid from the barrel chamber, as is best seen in Fig. 7, which is the position illustrated in Fig. 6, with the piston plug 79 substantially abutted against the front structure cross wall 52.

Various types of index or scale means may be provided on the barrel 50 and the rear cap 82 to measure the amount of load or quantity of parenteral liquid drawn into the barrel bore or chamber 63 by retraction of the plunger assembly 75 and one such form is illustrated in the embodiment of Figs. 1 to 12 incl., a supplemental or alternative form being indicated in Fig. 10. Such index or scale means, as there illustrated, may comprise a series of circular ribs 90-90 arranged about the exterior surface of the rear cap 82 and preferably may be formed in the molding of the latter, with each suitably identified with volume indicia, such as "O cc", "½ cc", "1 cc", "1½ cc", and "2 cc". When one of the ribs 90 is brought to substantial alignment with the barrel groove 67 the volume of the barrel chamber 63 is substantially that of the volume mark on the rear cap 82 and this may be readily determined by observation when the rear cap is molded from transparent material, such as clear polystyrene or foggy polyethylene which in relatively thin section can be clearly seen through. In order to facilitate proper alignment of any particular cap rib 90 with barrel groove 67, the inner

wall of the rear cap may be provided with a plurality of pairs of diametrically-opposed nibs 91-91, each pair being associated with one of the ribs, as indicated in Figs. 1, 8, 10 and 11. When any particular cap rib 90 is brought to substantial alignment with barrel groove 67, the pair of diametrically-opposed internal nibs 91, 91 on the inner wall of the cap associated with this rib and lying substantially in the same transverse plane, as shown in Fig. 10, will snap into the barrel groove by virtue of the elasticity of either the barrel material or the cap and nib material, or of both. Such index or scale ribs 90-90 may also serve to facilitate manual grip of the plunger assembly 75.

Such index or scale means comprising plunger cap ribs 90-90 and cooperating barrel groove 67 may be supplemented by other scale or index means, such as that shown in Fig. 10, or such may be used in substitution for the other. As there indicated the scale may comprise suitable indicia or markings 190-190 imprinted on a side of the barrel 50 with which the transverse free edge 86 of one of the plunger cap legs 87 is to be successively aligned as an indicator element. Such index or scale means is particularly useful if it is desired to avoid problems of molding ribs 90-90 on plunger cap 82 and/or to form the latter from opaque material.

The parts of the hypodermic syringe device illustrated in Figs. 1 to 12 incl. preferably will be assembled for sterilization and then subsequent packing and use in the following manner. The barrel 50 with its fixed single-ended needle 55 will have applied to the front structure 51 thereof a needle-protective cap 69 which, as will be seen from Fig. 1, will be telescoped over the needle with the cylindrical rear end 72 of the cap slidably received within the cylindrical front flange 57. Such initial telescoping or slidable mounting of the cylindrical rear end 72 of the needle-protective cap 69 within the cylindrical front flange 57 will be only to a limited degree, as illustrated in Figs. 1 and 2, so that fluid passage is provided through the plurality of longitudinal grooves 60-60 in the inner wall of the front flange, thence into the unfilled portion of the annular groove 58 around behind and past the back edge 73 of the rear end of the cap, and then between the spaced inner wall of the cap cylindrical rear end 72 and the boss 53 to the space 74 within the needle-protective cap. This communicates the atmosphere exterior of the barrel 50 and cap 69 directly to the space 74 within the cap by a fluid passage or way. The space 74 within the cap 69 is in communication with the barrel chamber or bore 63 by way of the needle bore 92 which constitutes the liquid outlet passage of the barrel. The mounting of the plunger assembly 75 to the rear end of the barrel 50 disposes the piston plug 79 within the counterbore 65 of the barrel bore while providing space between the inner wall of the latter and the piston plug for free passage of fluid or gaseous medium, as illustrated in Fig. 1. This mounting of the piston assembly 75 to the rear end of the barrel 50 in the rearmost or fully retracted position, as illustrated in Fig. 1, leaves appreciable portions of the diametrically-opposed cap notches 85, 85 uncovered by barrel structure for free passage of fluid to and/or from the rear end of the latter.

A plurality of such hypodermic syringe assemblies, such as that illustrated in Fig. 1, are then suitably loaded into a closeable sterilizing tank. After loading of the sterilizing tank it is closed and the air therein and in the open syringe assemblies exhausted therefrom with simultaneous supply to the closed tank of suitable sterilizing fluid or gaseous medium, such as formalin, ethylene oxide or steam. When gaseous mediums other than steam are employed they may be heated, if desired. As a result, the sterilizing fluid or gaseous medium not only flows completely about each of the hypodermic syringe assemblies in the tank but also through the interior of each of the syringe assemblies by way of the open valved sterilizing-fluid passage at the front needle-protective cap 69 previously described, through the barrel bore or chamber 63, about the piston plug 79 and its supporting piston stem 76, and through the plunger assembly cap notches 85, 85. The sterilizing gaseous medium may then flow from the space 74 within the needle-protective cap 69 *via* the needle bore 92 into the barrel chamber or bore 63, from the latter past the constricting stop rib 64 through the clearance or space provided between the substantially cylindrical exterior surface of the piston plug 79 and the inner wall of the counterbore 65 into the space defined by the bore 83 of the plunger assembly rear cap 82, and thence through the diametrically-opposed notches 85, 85 in the skirt of the rear cap to tank atmosphere. Of course, the direction of flow of sterilizing gaseous medium may be in the reverse direction or a combination of both directions as the air in the syringe assembly of Fig. 1 is withdrawn from the sterilizing tank for replacement by the sterilizing gaseous medium.

After sterilization of the plurality of assemblies of the type shown in Fig. 1 in the sterilizing tank, the latter is opened by the operator and the interiors of the assemblies immediately closed off by a simple procedure of pushing the piston assembly 75 of each forward to its extreme forward closing position and then pushing the needle-protective cap 69 of each back to its rearmost closing position, as illustrated in Fig. 6. It will be noted that with the needle-protective cap 69 pushed completely back so that its cylindrical

rear end 72 is wedged into the bottom of annular groove 58, a fluid seal is provided at the root of the boss 53 and the exterior surface of the edge of the cap is lapped by the uninterrupted cylindrical surface of the zone 61 of the interior wall 59 of projecting front flange 57. It will also be noted that the back edge 68 of the barrel is wedged into the annular groove 84 between the inner surface 83 of the piston cap wall and the frusto-conical plug 81, securely closing off the rear end of the barrel chamber 63. A molded cylindrical bore has slight taper to permit withdrawal of the core and thus any barrel bore will be of slightly less diameter at the closed end than at the free edge. For example, in a working model of the present syringe the barrel bore may be about *1.375* inches long having a diameter at the front cross wall 52 of about *0.370* inches and in the vicinity of stop rib 64 of a diameter of about *0.375* inches. Similar taper would be provided in the molding of the bore 83 of the plunger rear cap 82, and thus in the absence of the plugging element 81 at the root of the piston stem 76 secure fluid seal will be attained by wedging between the exterior surface of the back edge 68 of the barrel 50 and the interior surface of the plunger cap bore adjacent the root of the piston stem. However, wedging of the plugging element 81 into the counterbore 65 of the barrel assures a secure fluid seal thereat with a tendency for the plugging element slightly to spread the back edge 68 of the barrel and press its exterior surface more securely against the surface of cap bore 83. The sterilized assembly of Fig. 6 is then packaged for distribution.

In use and operation of the assembly of Fig. 6, the physician or the person who is to administer an injection of parenteral liquid will withdraw the needle-protective cap 69 and discard it. He then thrusts the needle point 56 through the pierceable seal of a suitable multi-dose container, indicated in dotted lines at 93 in Fig. 9, and retracts the plunger assembly 75 to a position dictating a capacity of the syringe chamber substantially equivalent to the volume of the injection to be administered, say *2 cc's*; e.g. where the "2 cc" rib 90 becomes aligned with the barrel groove 67, and with the internal diametrically-opposed nibs 91, 91 opposite that rib snapping into that groove, or when cap leg edge 86 aligns with "2 cc" mark 190 on the side of the barrel. Suction created on the barrel chamber 63 will cause the parenteral liquid to be drawn up from the container 93 into the barrel chamber and the syringe device will thus be loaded for use, such loaded syringe assembly being illustrated in Figs. 10 and 11 with the *2 cc's* volume of parenteral liquid indicated in the latter at 94. The needle tip 56 will then be thrust into a patient's flesh, such as that indicated at 95 in Fig. 12, and if the parenteral liquid is of the intravenous type, the usual aspirating precautions for a show of blood will be taken to assure that the needle bore is in communication with a vein, such as that indicated at 96 in Fig. 12. The person administering the injection grasps the barrel 50 in front of the finger wings 89, 89 between two fingers and with his thumb applies thrust to the back end 97 of the plunger assembly cap 82 to expel the parenteral liquid 94 from the syringe barrel 50 through the needle bore 92 into the patient's vein by piston action or forward travel of the piston plug 79.

When syringe assemblies are successively loaded in such fashion from multi-dose supply containers, such as that illustrated at 93 in Fig. 9, it is a common practice to replace withdrawn parenteral liquid with atmospheric air to avoid creating a partial vacuum or low pressure conditions in the container which would tend to resist effective syringe-loading suction on the parenteral liquid contents of the supply container. This is usually done by retracting or drawing the piston back to fill the syringe chamber with atmospheric air and then after the needle is thrust through the pierceable seal or closure of the supply container thrusting the piston forward to expel the chamber air into the supply container. Thereafter, the piston is then again retracted to draw parenteral liquid into the syringe chamber; and the syringe is then injectively used in the above-indicated manner. Such practice of pumping atmospheric air into the supply container frequently causes sufficient concentration of airborne bacteria eventually to be developed in the supply containers as to cause mold growth and spoilage of parenteral liquid therein. The assemblies of the present invention may be employed in a manner to avoid any such tendency to cause spoilage and mold growth, while permitting pumping of gaseous medium such as air into the supply containers at the time syringes are to be loaded with parenteral liquid therefrom. For example, after sterilization of the Fig. 1 assembly the piston assembly may be thrust forward until its piston head means or plug 79 passes just beyond stop rib 64 to the full line position of Fig. 11, whereby the back end of the barrel bore 63 is effectively closed in a fluid-tight manner but the syringe chamber contains about *2 cc's* of sterile gaseous medium, maintained entrapped therein by subsequent thrust rearward of the needle-protective front cap 69 to the Fig. 6 position. Thus the sterilized and sealed syringe assemblies of the present invention, such as the embodiment of Figs. 1 to 12 incl., may be distributed to the ultimate operators either in an empty condition, wherein the closed barrel chamber has practically no fluid content with the piston means juxtaposed to the front struc-

ture, or in a sterile fluid-containing condition so that sterile gaseous medium in the sealed barrel chamber may be pumped into the multi-dose supply container at the time the barrel chamber is loaded with parenteral liquid.

If it is desirable to mold the piston cap 82 and piston stem 76 as an integral unit from a somewhat elastic plastic, such as polyethylene, it may be found that the diametrically-opposed legs 87, 87 of the piston cap are more flexible than that desired to assure that the latter will remain, during handling and sterilizing, securely mounted on the rear end of the barrel 50, such as in the position of Fig. 1. The piston cap legs such as 187, 187 of Fig. 13, may be stiffened to avoid such accidental disengagement, such as by thickening the stock thereof, which may be accomplished by providing longitudinally-extending exterior stiffening ribs 98, 98, as shown in Fig. 13. Such expedient of stiffening the piston cap legs 187, 187 may be particularly desirable if the lower edges 86, 86 of such legs are narrowed or rounded off to provide camming surfaces for camming engagement of the finger wings 89, 89 in forward thrust of the plunger assembly 75, so as to prevent the finger wings from stopping the piston action before complete expulsion of the chamber contents; and, if desired, such piston cap legs may be extended so that when the plunger assembly is in its fully retracted or rearmost position portions thereof will always remain interdigitated with respect to the finger wings.

As illustrated in Figs 14 to 17 incl., the finger wings may be separately mounted to the barrel 150 rather than being molded integral therewith. As illustrated in Figs. 14 and 15, the finger wings are provided by a separate piece 98 having an apertured mid-portion 99 provided with a through hole 100 which slidably receives a stepped front section 101 of the barrel 150 to abut against a circular shoulder 101' provided by the barrel stepping for locating the finger wings 189, 189 flanking the mid-section 99 in the desired position along the barrel.

Also as indicated in Figs. 14 to 17 incl., the valved sterilizing-fluid passage at the front cap means may be provided in a modified form. As there illustrated, the needle-protective cap 169 has a cylindrical side wall 171, the cylindrical rear end 172 of which is provided with a longitudinally extending notch 102. The front structure 151 of the barrel 150 has a forwardly-extending coaxial flange 57 defined by an outermost cylindrical inner wall section 159 and an innermost frusto-conical inner surface 103 merged therewith. The needle boss 153 has an exterior frusto-conical surface 104 at its root which defines with the surface 103 a tapered annular groove bottom 158 into which the free edge 173 of the needle-protective cap 169 is to be wedged in the valve closing position. As illustrated in Fig. 16, in the initial assembly of the parts of the hypodermic syringe device of the Figs. 14 to 17 incl., embodiment a relatively short zone of the side wall free edge 172 of the needle-protective cap 169 is telescoped into the cylindrical section 159 of the inner surface of the front flange 157 for holding the parts together temporarily and with a portion of the notch 102 uncovered or open. Thus, the space 74 within the cap 169 communicates directly with the atmosphere surrounding the syringe assembly through the uncovered portion of notch 102, as indicated in Fig. 16. After the hypodermic syringe assembly of the Figs. 14 to 17 incl., embodiment has been suitably sterilized, such as in the manner indicated above, the needle-protective cap 169 will be pushed forward to wedge its cylindrical rear end 172 within the tapered annular groove bottom 158, as indicated in Fig. 17, thereby securely closing off in a fluid-tight manner the sterilizing-fluid passage provided by the notch 102.

A further embodiment of the invention is illustrated in Fig. 18 and as there shown the front structure 251 of the barrel 250 is provided with a stepped axially-extending neck 105 having a tapered tip 106 which may be wedgably telescoped into a tapered socket 107 in hub 108 of a removable needle 155 to communicate the needle bore 192 with neck bore 109 which leads to barrel chamber 163. The needle-protective cap 169 is similar in structure to that described in the Figs. 14 to 17 incl., embodiment, having a cylindrical rear end 172 of cylindrical side wall 177 provided with notch 102 to serve as a valved sterilizing-fluid passage at the cap. The edge zone 172 of the cap telescopically receives a substantially cylindrical enlargement 110 of the stepped neck 105 and when the cap 169 is in the position illustrated in full lines in Fig. 18 a portion of the notch 102 remains uncovered to permit fluid to pass therethrough from the atmosphere surrounding the assembly to the space 74 within the cap. After the assembly is sterilized in a manner such as that indicated above, the cap 169 will then be pushed forward to the dot-dash position indicated at 172' in Fig. 18 so that the notch 102 and fluid passage provided thereby is wholly closed by complete lap of the circular land or enlargement 110 of the neck.

If it is desirable that all exterior surfaces of the tapered tip 106 of neck 105 in Fig. 18 which are to be socketed into and lapped by the internal wall of a needle hub socket, such as 107 of the hub 108, of a removable needle unit, such as 155, be sterilized by sterilizing fluid, this may be readily accomplished by having the needle unit initially loosely disposed or housed within the front protective cover 169. The front protective cover or cap

169 may be of such length with respect to the length of the needle unit that when the cap is pushed to its rearmost position for closing the sterilizing fluid passage leading to the exterior thereof, it will carry with it rearwardly the needle unit to socket the hub 108 of the latter over the barrel neck 105 to a jamming secure position. For this purpose, the tapered tip 106 of the neck 105, needle unit 155 and its hub 108 may be of such relative dimensions and lengths that in the initial position with the needle tip in the vicinity of the closed outer front end of the front protective cap 169, the very tip 106 of the neck 105 is loosely disposed within the mouth at the rear end of the hub socket 107, so as to guide the subsequent telescopic jamming of the tapered neck tip within the hub socket upon rearward thrust of the front protective cap.

In embodiments of the present invention it may be important to sterilize all surfaces of the needle cap which may be brought, even accidentally, into contact with any portion of the needle which is to be inserted in a patient's flesh so that there can be no possibility of contamination of the insertable portion of the needle by the person who is to administer the injection when he removes the needle protective cap from the sterilized assembly for loading and subsequent injective use. For example, any zone of the inner wall of the cap, such as that adjacent the free edge thereof, which may have lapped the barrel structure or front structure of the latter during the sterilizing process may not have during the latter become completely sterilized and when the cap is withdrawn, the latter may be dragged against the tip of the needle to tend to contaminate it. As shown in Figs. 19 to 22 incl., such possibility of contamination may be eliminated with assurance by mounting a needle guide means within the needle-protective cap with the guide having its parts, which may drag against the needle during cap withdrawal, thoroughly sterilized and preventing contact between the needle and any portion of the cap which may not have become thoroughly sterilized during the sterilizing process. For example, the syringe barrel 350 has a front structure 351 provided with an external annular groove 111 and with the adjoining surfaces of the front structure being substantially cylindrical for sliding lap with the cylindrical inner surface 112 of rear end 272 of a needle-protective cap 269. The needle-protective cap 269 has two sets of diametrically-opposed or a plurality of radially-spaced nibs 113-113 and 114-114 with the former set of nibs being located nearest the free edge 273 of the cap. When the cap 269 has its cylindrical side wall 271 telescopically assembled to the barrel 350 in its initial sterilizing position as illustrated in Fig. 19, the set of nibs 113-113 snap into the barrel annular groove 111 securely to hold the parts together. In such position a plurality of apertures 115-115 extending through the side wall 271 near the free edge of the cap 269 or edge zone 272 thereof remain uncovered and open to provide communication directly between the atmosphere exterior of the barrel and cap and the space 74 within the latter so that sterilizing gaseous medium may flow through such cap side holes, the space within the cap and the bore of needle 55 to the barrel chamber 63. In the Figs. 19 to 22 incl. embodiment, needle guide means 116 is provided which is in the form of an elongated strip of semi-rigid elastic material, such as a spring strip of semi-rigid plastic such as that sold under the registered Trade Mark, Vinylite, etc. Such needle guide strip 116 has a medial needle-receiving aperture 117 to permit it to be slipped loosely down over the needle 55, and its opposite ends 118, 118 are to be folded back or bent toward each other, as indicated partially in dot-dash lines in Fig. 19. The bent back ends 118, 118 of the needle guide strip 116 will then be received within the cylindrical side wall 271 of cap 269 as it is telescoped backward to lap the barrel front 351 and in doing so a reverse bend, such as that indicated at 119, is formed in the medial portion of the strip adjacent the needle-receiving aperture 117.

In operation of the embodiment illustrated in Figs. 19 to 22 incl., after the assembly has been sterilized with the cap 269 in an initial valve-open position relative to the barrel 350, as illustrated in Fig. 19, the cap will be telescoped farther back upon the barrel front structure 351, such as to the valve-closing position illustrated in Fig. 22, until the second set of internal nibs 114-114 snap into the barrel front groove 111 to hold the parts in their relative positions of closure of the valved sterilizing-fluid passage provided by the side holes 115-115. This increases the lap by the cylindrical rear end 272 of the cap relative to the substantially cylindrical barrel front structure 351 to close off the passage holes 115-115 in a substantially fluid tight manner. The set of nibs 113-113 and 114-114 do not interfere with such telescopic movement of the cap 269 relative to the barrel front structure 351 if the cap is molded from material having some elasticity so that the small localized nibs will readily flatten out when pressed against barrel structure and for this purpose the cap and its nibs may be molded integrally from elastic plastic, such as polyethylene. In telescoping the needle-protective cap 269 from the initial valve-open position illustrated in Fig. 19 to the valve-closing position illustrated in Fig. 22, the foreshortening of the space 74 within the cap causes some accommodating distortion of the needle guide strip 116, such as an exaggeration of the reverse bend 119 in the

mid-portion of the strip adjacent the needle hole 117, as illustrated in Fig. 22.

Assume sterilization of the hypodermic syringe assembly of the Figs. 19 to 22 incl. embodiment in a manner such as that described above when the parts are in their relative positions illustrated in Fig. 19 and subsequent closing of the valved sterilizing fluid passage provided by the cap side holes 115-115 by inward thrust of the cap 269 to the position of Fig. 22 and distribution of the sterilized assembly to a user, then the user, in preparing to load the syringe barrel chamber 63 with a body of parenteral liquid, will withdraw the cap 269 from the barrel front structure 351 and the needle 55. The portion of the inner wall of the cylindrical rear end 272, which lapped the exterior surface of the head structure 351 in the position of Fig. 19 during sterilization, perhaps would not be effectively sterilized. Thus, in withdrawing the cap 269 from off the needle 55 the user might accidentally drag such contaminated inner zone of the cap against the needle tip 56 in the absence of the needle guide strip 116. However, with the needle guide strip 116 present in the cap 269 withdrawal of the cap permits the reverse bend 119 of the medial portion of the strip 116 to relax and reverse to an arched position similar to that indicated in dot-dash lines in Fig. 19, and upon further withdrawal the needle 55 slides out of the central hole 117 of the guide strip and is prevented from moving laterally or radially in any direction thus keeping its tip 56 out of contact with the contaminated zone of the inner wall of the cap.

It is to be understood that embodiments of the hypodermic syringe of the present invention may be provided in forms which do not require injective needles, or in which the injective needles are supplied separately to be removably fitted to the barrel front structures such as is the case of needles having socketed hubs which frictionally receive tapered outlet necks extending from the barrel front structures with the neck bores communicating with the barrel chambers to serve as the outlet passages for the latter. It is obvious that embodiments of the invention may employ plunger means in which the piston stem and piston head are made integral with each other, being molded in one piece, if desired, from suitable elastic material.

When plastic materials are employed which can withstand considerable heat without undue or distortional softening sterilization of an assembly of the invention may be accomplished by heat radiation and/or conduction with the construction or assembly in closed condition so that after such heat sterilization the closed condition will maintain until use the sterile condition of the sterilized closed assembly. Thus, for example, the assembly of Figs. 1 to 12 incl. may be so sterilized by heat when the assembly is in the closed condition of Figs. 6 and 7. In the Figs. 14 to 17 incl., embodiment such heat sterilization will be accomplished with the parts in the relative closed positions of Fig. 17. Heat sterilization of the Fig. 18 embodiment may be effected with the protective cap 169 in the dot-dash position indicated at 172'. Since heat sterilization effectively sterilizes lapped surfaces the embodiment of Figs. 19 to 22 incl., may be heat sterilized when in the closed Fig. 22 condition, and in such case needle-guiding means, such as strip 116, is not needed since all surfaces of cap 269 are freed from contamination and the interior surfaces remain sterile.

In all embodiments illustrated in the drawings one of the cap and barrel means has blocking means preventing flow of bacteria-laden air through the front end sterilizing-fluid flow passages into the interiors of the sterilized assemblies.

The blocking means for the rear end flow passage of the illustrated embodiments is provided as cooperating interengaging means of the barrel means and the plunger subassembly (including the plunger stem, the surrounding hood and the distal or rear end connection thereof), in the form of a valve structure at the root of the plunger stem. However, such blocking means may be located elsewhere along the rear end flow passage, such as between the hood and the exterior of the barrel. For example, the barrel wall may carry an external annular flange as a base on which the finger grasps or wings are mounted, or as a separate element located therebehind, against which the free front edge of the hood is jammed or with which it is interfitted.

WHAT I CLAIM IS:—

1. A sterilized hypodermic syringe assembly including barrel means having a front end cross wall structure and together with said barrel means defining a chamber for containing parenteral liquid, the rear end of the barrel means terminating in a circumambient structure defining an open chamber rear end, the front end having a liquid outlet passage communicating with the chamber for injective discharge of liquid contents, removable protective cap means supported by the front end and isolating the outlet passage from airborne bacteria in the surrounding atmosphere exterior of the barrel and cap means, with said cap means being of a structure to provide in one position thereof a sterilizing-fluid flow passage extending from the exterior to the interior of the cap means and in another position thereof closure of said flow passage, plunger means reciprocably mounted in the chamber through its open rear end, and cooperative blocking means on the plunger means and the barrel

means closing off fluid communication between the rear end of the chamber and the surrounding atmosphere when the plunger means is in forward position in the chamber so as to prevent flow therethrough of bacteria-laden air from the surrounding atmosphere into said chamber.

2. An assembly according to claim 1, wherein said plunger means includes piston means slidably mounted in a forward position in the chamber for drawing fluid thereinto upon retraction to a rearward position and expelling fluid therefrom upon forward thrust to its forward position, elongated plunger stem means extending through the open rear end of the chamber and carrying the piston means on its front end, and an elongated hood having an open front end with its rear end being closed and carried by the rear end of the plunger stem means, the hood surrounding a major portion of the stem means with an annular space defined therebetween into which the rear end of the barrel means is telescoped with a rear portion of the barrel means protectively housed by overlap thereby, the housed barrel portion and the plunger means being relatively shaped to provide therebetween a rear sterilizing-fluid flow passage leading from the surrounding atmosphere at the front end of the hood between the latter and the housed barrel portion to the open rear end of the latter for communication to the chamber when the plunger means is retracted to its rearward position with the piston means in such position permitting pressure flow therepast of sterilized fluid into and out of the chamber, said cooperative blocking means closing off said rear flow passage when the plunger means is in said forward position.

3. An assembly according to claim 2, wherein the blocking means for the rear flow passage includes valve means having cooperating interengaged elements at the rear end of said plunger stem means and at the rear end of said barrel means.

4. An assembly according to claim 3, wherein said interengaged elements are the circumambient rear end structure of the barrel means and a plugging element intervening the rear of the stem means and hood, the plugging element being jammed into the circumambient rear end structure.

5. An assembly according to any one of claims 2 to 4, including cooperating stop means on the barrel means and the plunger means to limit retraction of the latter to the rearward position with maintenance of a degree of overlap of the free front end of the hood on the rear end of the barrel means.

6. An assembly according to any one of claims 2 to 5, wherein said piston means is snugly fitted in the barrel bore and said piston stem means is coaxially received in said bore, the hood coaxially surrounding said barrel and having its rear end circumferentially attached to the rear end of said piston stem means, the rear edge of the barrel means being fitted in said annular space in a fluid-tight manner when said piston means is moved to its forward position.

7. An assembly according to any one of the preceding claims, wherein the structure of the rear of the cap means and the front end of the barrel means include engaged cooperating valve elements, the cap means rear end and the front end of the barrel means being movable relative to each other with maintenance of the mount of the cap means on said front end to a position wherein the said valve elements are separated, for opening the front end flow passage.

8. An assembly according to any one of the preceding claims wherein the barrel means includes an elongated cylinder having a bore, the front end thereof including a structure closing off the front end of the bore, a hollow injective needle being carried by and extending coaxially from the front end structure with the lumen thereof in communication with the liquid chamber, said cap means being elongated and telescoped over the needle and removably fitted to said front end structure and having a tip extending beyond the free end of the needle.

9. An assembly according to claim 8, wherein said front end structure includes an axially extending annular flange arranged about the needle and extending forward from said front end structure, and said cap means has a free edge zone adapted for telescoping with said flange to cut off communication of said needle and the front end of said barrel with the outside atmosphere.

10. An assembly substantially as described herein and with reference to Figs. 1 to 13 of the drawings.

11. An assembly substantially as described herein and with reference to Figs. 14 to 17 of the drawings.

12. An assembly substantially as described herein and with reference to Fig. 18 of the drawings.

13. An assembly substantially as described herein and with reference to Figs. 19-22 of the drawings.

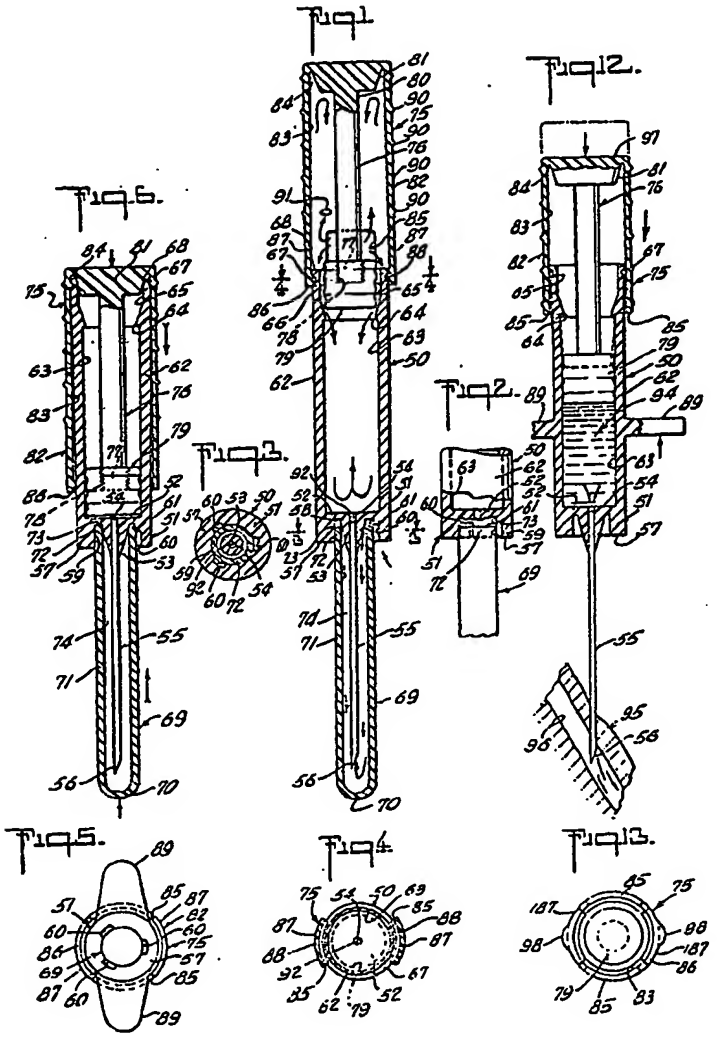
MARKS & CLERK.

Bournemouth: Printed for Her Majesty's Stationery Office, by Richmond Hill Printing Works Ltd.—1960.
Published at The Patent Office, 25, Southampton Buildings, London, W.C.2, from which copies may be obtained.

847914 COMPLETE SPECIFICATION

3 SHEETS *This drawing is a reproduction of the Original on a reduced scale*

Sheet 1



847914
3 SHEETS
COMPLETE SPECIFICATION
This drawing is a reproduction of the Original on a reduced scale
Sheets 2 & 3

Fig.7.

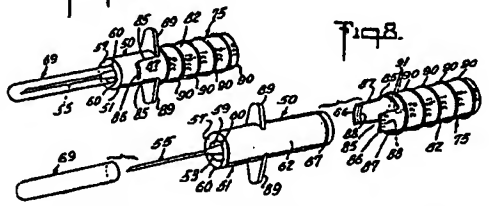


Fig.8.

Fig.11.

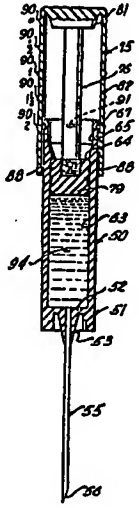


Fig.10.

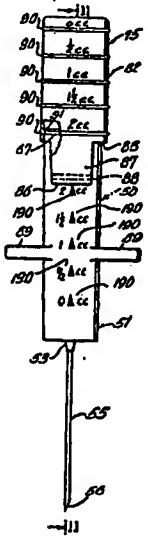


Fig.9.

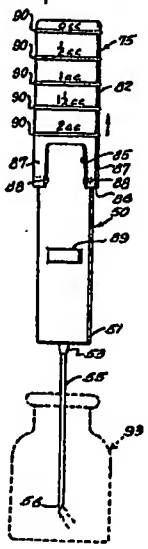


Fig.14.

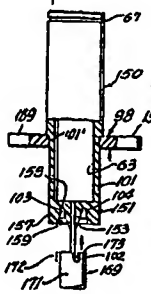


Fig.15.

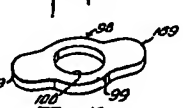


Fig.16.

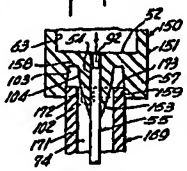


Fig.17.

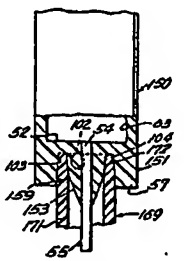


Fig.18.

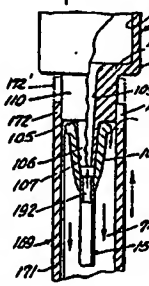


Fig.22.

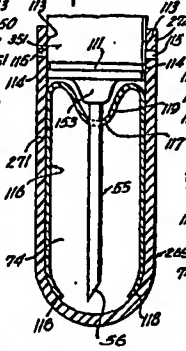


Fig.19.

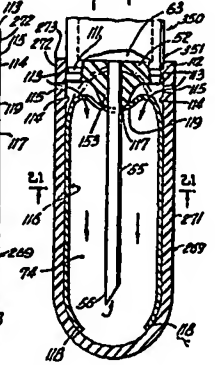


Fig.21.

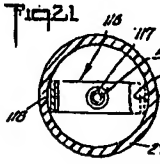


Fig.20.

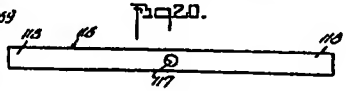


Fig. 7.

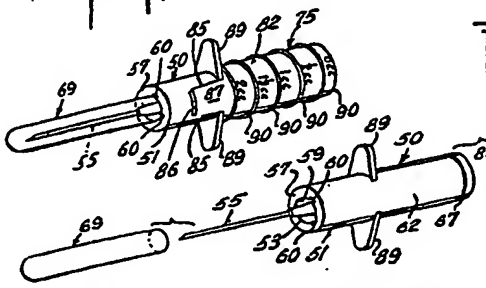


Fig. 8.

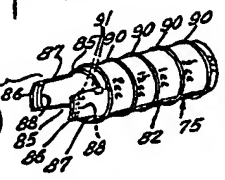


Fig. 11.

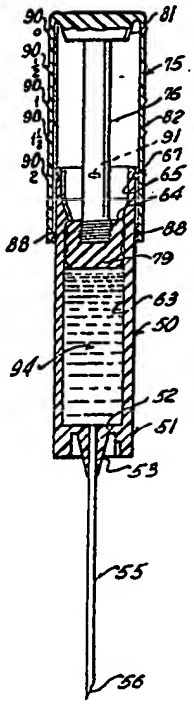


Fig. 10.

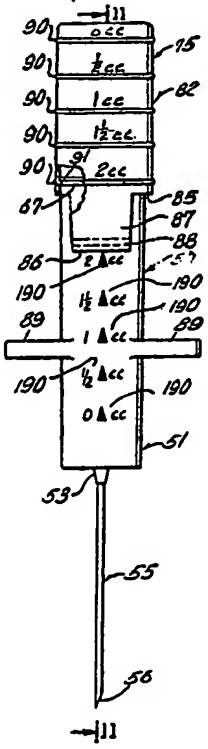
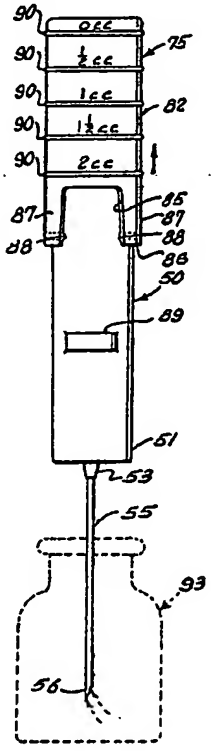


Fig. 9.



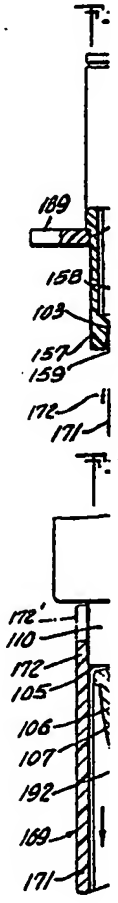
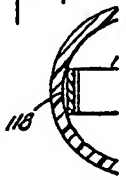


Fig. 21.



847914
3 SHEETS

COMPLETE SPECIFICATION
This drawing is a reproduction of the Original on a reduced scale
Sheets 2 & 3

Fig 14.

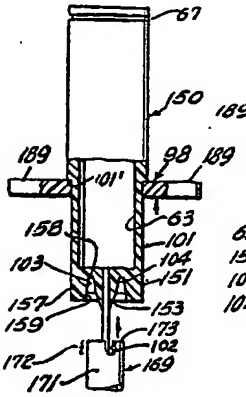


Fig 15.

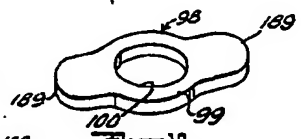


Fig 16.

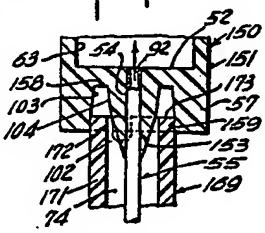


Fig 17.

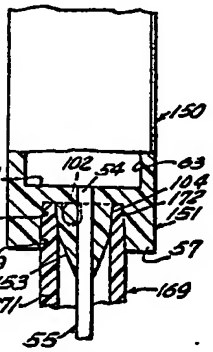


Fig 18.

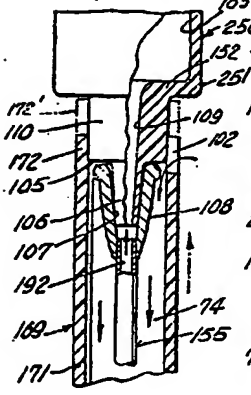


Fig 22.

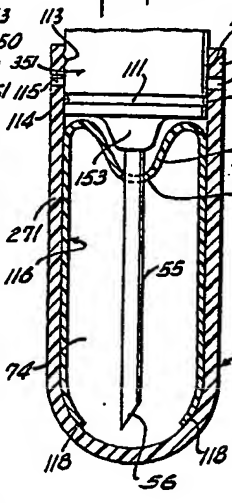


Fig 19.

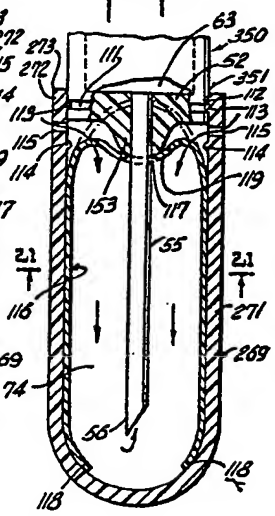


Fig 21.

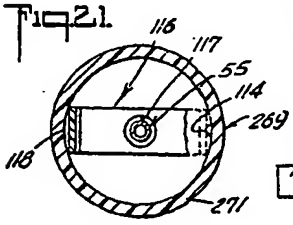


Fig 20.